

MTF Formulary Management for the Antilipidemic II Agents (LIP-2s)

Department of Defense Pharmacoeconomic Center

Bottom Line:

- Fenoglide (fenofibrate meltdose) was added to the BCF at the Jun 2008 DoD P&T Committee meeting; Triglide (fenofibrate insoluble drug delivery microparticle; IDD-P) was removed from the BCF, but is still UF.
- Tricor, Antara, Lovaza and Welchol remain NF drugs.
- Use gemfibrozil (also BCF), Fenoglide, or niacin to reduce triglyceride (TG) and increase HDL.

Uniform Formulary Decision: The Director, TMA approved recommendations from the May 07 DoD P&T Committee meeting. The Director approved the BCF designation of Fenoglide on 27 August 2008.

Uniform Formulary (UF) Agents		Non-Formulary Agents
LIP-2s on BCF MTFs <u>must</u> have on formulary	LIP-2s not on BCF MTFs <u>may</u> have on formulary	MTFs <u>must not</u> have on formulary
Gemfibrozil (Lopid) Fenofibrate meltdose (Fenoglide) – Jun 08 update	Fenofibrate IDD-P (Triglide) – Jun 08 update (removed from BCF) Fenofibrate micronized (Lofibra, generics) Fenofibrate non-micronized (Lofibra, generics) Cholestyramine (Questran, Questran Light, generics) Colestipol (Colestid)	Fenofibrate micronized (Antara) Fenofibrate nanocrystallized (Tricor) Prescription omega-3 fatty acids (Lovaza*, formerly Omacor) Colesevelam (Welchol)

IDD-P: Insoluble drug delivery micro particle

* Omacor brand name change to Lovaza July 2007

June 2008 DoD P&T Committee Meeting Update – Fibric Acid Derivatives

- MTFs should maximize the use of gemfibrozil or Fenoglide (fenofibrate meltdose) if a fibric acid derivative is needed.
- Fenoglide (fenofibrate meltdose) is a new fenofibrate formulation which has replaced Triglide (fenofibrate IDD-P) on the BCF (gemfibrozil is still designated BCF). Both Fenoglide and Triglide are manufactured by the same company, however Fenoglide uses different technology to enhance absorption than Triglide.
- Bioequivalency ratings of all fenofibrate formulations are based on the original 200 mg fenofibrate product (earliest Tricor version). Fenoglide is available in 40 mg and 120 mg tablets, which have the same bioavailability as Triglide 50 and 160 mg, respectively and Tricor 48 mg and 145 mg. See table below for dose equivalency chart.
- Fenoglide is dosed once daily, but should be administered with food to enhance absorption.
- Fenoglide has advantages over Triglide in that it does not require dispensing in moisture-proof containers, and is available in 90 count bottles (Triglide is only available in 30 count bottles).
- Triglide (fenofibrate IDD-P) was removed from the BCF due to back-order supply issues, and patient complaints of excessive tablet crumbling/friability. It remains on the UF.

Fenoglide Dose Equivalency Chart

Fenoglide 40 mg is equivalent to	Fenoglide 120 mg is equivalent to
Triglide 50 mg Tricor 48 mg non-micronized Lofibra 54 mg micronized Lofibra 67 mg Antara 43 mg	Triglide 160 mg Tricor 145 mg non-micronized Lofibra 160 mg micronized Lofibra 200 mg (No Antara dose is equivalent to above)

For example the equivalent doses to Tricor 145 mg are Fenoglide 120 mg = Triglide 160 mg = Lofibra 160 mg = micronized Lofibra 200 mg).

Background

- The LIP-2 drug class is comprised of the fibric acid derivatives (gemfibrozil, fenofibrate), prescription omega-3 fatty acids, and bile acid sequestrants (BAS; cholestyramine, colestipol, and colesevelam).
- Fibric acid derivatives and Rx omega-3 fatty acids primarily target triglycerides (TG), while the BAS target LDL.
- Statins, ezetimibe (Zetia), simvastatin/ezetimibe (Vytorin), and niacin were previously reviewed for UF placement as the Antilipidemic I (LIP-1) drug class in August 2006 (refer to http://www.pec.ha.osd.mil/drafts/UF_Info_May07changes.htm for more information).

Prescription omega-3 fatty acids Lovaza (formerly Omacor)

- Lovaza is the only prescription omega-3 fatty acid. The former Omacor brand name was changed due to confusion with the hemostatic agent aminocaproic acid (Amicar). It is FDA-approved for use in patients with elevated TG levels > 500 mg/dL.
- The DoD P&T Committee recommended use of gemfibrozil, fenofibrate and niacin over Lovaza or any OTC fish oil supplement for elevated TG levels. TG reductions with Lovaza are slightly less than that of the fibric acid derivatives or niacin. Lovaza is also associated with LDL increases, which may offset beneficial TG reductions.
- The DoD P&T Committee concluded there is insufficient evidence to support a cardiovascular benefit from omega-3 fatty acids. The DoD P&T Committee decision to make Lovaza non-formulary is not an endorsement for addition of OTC fish oil supplements to local MTF formularies.

Bile Acid Sequestrants (BAS)

- BAS may be alternatives for patients intolerant of statins. Cholestyramine is the only BAS with outcomes data showing a reduction in cardiovascular events (e.g., death, MI).
- There is no evidence to suggest that the non-formulary product colesevelam has improved efficacy compared to cholestyramine and colestipol.
- Colesevelam is the only BAS that has a pregnancy category B rating. It may also be preferred in patients with a history of GI obstruction.

Medical Necessity

- Medical necessity criteria apply to Antara, Tricor, Lovaza (formerly Omacor), and Welchol. Specific criteria are available on the TRICARE Pharmacy website at www.tricare.mil/pharmacy/medical-nonformulary.cfm.

Antilipidemic IIs (LIP-2s) MTF Price Comparison		
Drug	Weighted Avg cost/day (April 08) ^{ab}	
Basic Core Formulary LIP-2s	MTF Cost	System Cost ^c
Gemfibrozil (Lopid, generics)	\$0.17	\$0.27
Fenofibrate melfdose (Fenoglide)	\$0.44	\$0.95
Other UF LIP-2s available for inclusion on MTF formularies		
Fenofibrate IDD-P (Triglide)	\$0.48	\$1.47
Fenofibrate micronized (Lofibra, generics)	\$0.83	\$1.39
Fenofibrate nonmicronized (Lofibra, generics)	\$0.93	\$1.60
Cholestyramine sucrose (Questran, generics)	\$1.99	\$3.02
Cholestyramine aspartame (Questran Light, Prevalite, generics)	\$0.95	\$1.40
Colestipol (Colestid, generics)	\$1.00	\$1.53
Non-formulary LIP-2s		
Fenofibrate micronized (Antara)	\$1.85	\$2.93
Fenofibrate nanocrystallized (Tricor)	\$1.83	\$3.10
Prescription omega-3 fatty acid (Lovaza, formerly Omacor)	\$1.96	\$2.94
Colesevelam (Welchol)	\$2.57	\$3.85

^a Post-decision prices; actual price may vary slightly due to MTF-specific Prime Vendor discounts and/or fees

^b MTFs are prohibited from entering into any incentive pricing agreements in any form with LIP-2

pharmaceutical manufacturers to receive additional discounts.

^c System costs are the average weighted daily cost across all 3 points of service (MTF, Retail Network, TMOP)

References

- DoD P&T Committee minutes are available at http://www.pec.ha.osd.mil/PT_Committee.htm
- Current/future drug classes under review by the DoD P&T Committee: www.pec.ha.osd.mil/PTCommittee.htm
- TRICARE website for information on the Uniform Formulary: www.tricare.osd.mil/pharmacy
- TRICARE Formulary Search Tool: www.tricareformularysearch.org

For more information about this drug class review, email the PEC Staff at: PECUF@amedd.army.mil.